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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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February 6, 2019

Mr. Olivier Brandicourt
Chief Executive Officer
Sanofi
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Brandicourt,

We write to you today as part of our examination of the rising costs of health care, including the rising price of prescription drugs. As part of this work, we are seeking information to better understand insulin price increases.

Total health expenditures in the U.S. have increased substantially over the past several decades and are projected to continue to increase.[1] For instance, the Centers for Medicare & Medicaid Services' (CMS) data shows that total U.S. health expenditures were about $721 billion in 1990, $1.4 trillion in 2000, $2.4 trillion in 2008, and $3.3 trillion in 2016.[2] Moreover, CMS projected that, in 2018, total U.S. health expenditures would be about $3.68 trillion, and that, by 2026, total health expenditures would reach nearly $5.7 trillion.[3] Health care expenditures are spread across numerous services and products—in 2016, about 32 percent of the $3.3 trillion in spending was on hospital care, 20 percent was on physician and clinical services, 10 percent was on prescription drugs, and the remaining amount was on other services and products.[4]

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[1] Rabah Kamal and Cynthia Cox, *Peterson-Kaiser Health System Tracker, How has U.S. spending on health care changed over time?*, PETERSON CENTER ON HEALTHCARE AND THE HENRY J. KAISER FAMILY FOUNDATION (Dec. 20, 2017), *available at* https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#item-start.

[2] *Id.*

[3] Centers for Medicare & Medicaid Services, *NHE Fact Sheet* (last updated April 17, 2018), *available at* https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

[4] Centers for Medicare & Medicaid Services, *National Health Expenditures 2016 Highlights* (2018), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

The high cost of health care is a top concern for Americans, and many individuals have worried about the affordability of prescription medicines.[5] For instance, the Kaiser Family Foundation found that, in 2015, about 20 percent of Americans did not fill at least one of their prescriptions due to affordability concerns and other individuals rationed their medicines.[6] While the growth in prescription drug spending slowed in 2016 after two years of strong growth, CMS predicts that spending growth among the major sectors of health care over the next decade will be the fastest for prescription drugs.[7]

There have been increases in the cost of prescription drugs in many categories of medicines, including medicines targeted at treating life-threatening or chronic conditions like cancer, diabetes, and multiple sclerosis.[8] One medicine that has received a lot of attention due to list price increases is insulin;[9] according to a 2016 study, the average list price of insulin nearly tripled between 2002 and 2013.[10] The Congressional Research Service recently reported that the price of one type of insulin increased by 585 percent between 2001 and 2015.[11] While the Committee on Energy and Commerce has heard on numerous occasions that list prices do not accurately represent the true cost of prescription drugs since list prices do not account for the rebates and discounts that Pharmacy Benefit Managers (PBMs) and health plans typically negotiate with pharmaceutical companies, these list price increases are likely having a direct impact on patients.[12] Indeed, during the Committee's December 2017 hearing entitled "Examining the Drug Supply Chain," Members heard about how the complexity of the drug supply chain impacts patients and how much they pay for prescription medicines.[13] Specifically

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[5] National Academies Press, *Making Medicines Affordable: A National Imperative*, at 11 (2018); Julia Manchester, *Health care tops list of Americans' worries: poll*, THE HILL (Mar. 26, 2018), *available at* http://thehill.com/policy/healthcare/380249-healthcare-tops-list-of-americans-worries-poll.

[6] National Academies Press, *Making Medicines Affordable: A National Imperative*, at xvii (2018).

[7] Centers for Medicare & Medicaid Services, *National Health Expenditures 2016 Highlights* (2018), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf; Centers for Medicare & Medicaid Services, *CMS Office of the Actuary releases 2017-2026 Projections of National Health Expenditures* (Feb. 14, 2018), *available at* https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-2026-projections-national-health-expenditures.

[8] National Academies Press, *Making Medicines Affordable: A National Imperative*, at 104 (2018); Robert Langreth, et al., *After Raising Prices for 100s of Drugs, Industry Pledges Restraint*, BLOOMBERG (last updated Aug. 1, 2018), *available at* https://www.bloomberg.com/graphics/2018-drug-price-index/.

[9] R. Scott Rappold, *Spiking Insulin Costs Put Patients in Brutal Bind* (Jul. 25, 2018), *available at* https://www.webmd.com/diabetes/news/20180725/spiking-insulin-costs-put-patients-in-brutal-bind.

[10] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 2-3 & 11 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019; Xinyang Hua, MSc, Natalie Carvalho, PhD, Michelle Tew, MPH, et al., *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*, THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (2016), *available at* https://jamanetwork.com/journals/jama/fullarticle/2510902.

[11] Congressional Research Service, *Insulin Products and the Cost of Diabetes Treatment* (Nov. 19, 2018), *available at* https://fas.org/sgp/crs/misc/IF11026.pdf.

[12] *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong., Testimony of Lori M. Reilly, Executive Vice President, Policy, Research, and Membership, Pharmaceutical Research and Manufacturers of America (Dec. 13, 2017).

[13] *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, 15 (Dec. 13, 2017).

mentioning insulin, the Executive Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA), Ms. Lori M. Reilly, testified:

> Due to the growing gap between list and net prices, patients' cost sharing for medicines is increasingly based on prices that do not reflect plan sponsors' actual costs. For example, market analysts report that negotiated discounts and rebates can lower the net price of insulin by up to 50% to 70%, yet health plans require patients with deductibles to pay the full undiscounted price. As a result, a patient in a high-deductible health plan who pays the list price each month for insulin maybe paying hundreds—or even thousands—more annually than their insurer.[14]

Similarly, according to an analysis conducted by individuals from the USC Schaeffer Center for Health Policy & Economics, average out-of-pocket costs for all insulin types doubled between 2006 and 2013 for Medicare Part D beneficiaries.[15]

Ensuring that Americans have access to life-saving medicines not only requires considering the affordability of medicines for patients, but also accelerating the discovery, development, and delivery of medicines that provide cures for diseases and help individuals with chronic conditions live longer, healthier lives.[16] The pharmaceutical industry has made substantial investments to develop innovative medicines—a 2018 report indicated that the industry has invested about half a trillion dollars in research and development over the past decade.[17] Some recent advancements include, but are not limited to, oral treatments for hepatitis C that provide cure rates of more than 90 percent, the first drug to treat spinal muscular atrophy, the first lupus drug in 50 years, new oral treatment for multiple sclerosis, 16 new drugs to treat cancer in 2017, 2 new drugs for difficult-to-treat forms of high cholesterol in 2015, and the first drug to target the root cause of cystic fibrosis.[18] These vital medicines not only improve the quality of life for patients, but they also can generate health care savings by decreasing the number of hospitalizations and other costly medical procedures and services.[19] Indeed, according to a 2018 report issued by PhRMA, up to $213 billion of health care spending in the United States—8 percent of health care spending—could be eliminated by better use of medicines.[20]

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[14] *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong., Testimony of Lori M. Reilly, Executive Vice President, Policy, Research, and Membership, Pharmaceutical Research and Manufacturers of America (Dec. 13, 2017).

[15] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, DIABETES CARE, at 9 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019.

[16] PhRMA, *Chart Pack: Biopharmaceuticals in Perspective, Summer 2018* (Jul. 24, 2018), *available at* https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018; PhRMA, *2018 Profile: Biopharmaceutical Research Industry* (2018), *available at* http://phrma.org/industryprofile/2018/.

[17] PhRMA, *2018 Profile: Biopharmaceutical Research Industry* (2018), *available at* http://phrma.org/industryprofile/2018/.

[18] PhRMA, *Chart Pack: Biopharmaceuticals in Perspective, Summer 2018* (Jul. 24, 2018), *available at* https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018.

[19] *Id.*

[20] *Id.* at 114.

More than 30 million Americans have diabetes, and about 7.4 million of those individuals rely on some form of insulin.[21] A 2018 report on the economic costs of diabetes in the U.S. found that, out of the cost categories analyzed for that report, care for individuals with diagnosed diabetes accounted for approximately 24 percent of the health care dollars spent in the U.S. in 2017, and that more than half of those expenditures were directly attributable to diabetes.[22] Press articles have highlighted instances where individuals with diabetes have stopped taking insulin, switched to less effective formulations, or started rationing the medicine due to its high price and suffered adverse health consequences as a result.[23] One survey found that 45 percent of diabetics have gone without insulin due to its price.[24]

The Committee therefore requests your assistance in better understanding the relationship between insulin's list price and its negotiated price, the impact that this negotiation process has on patients and medication adherence, and medical advancements with insulin. Accordingly, as one of the three insulin manufacturers serving the U.S. market,[25] we request that you provide answers to the following questions by February 20, 2019:

1. **List price for insulin**. Manufacturers set the list price for insulin products. Federal statutes, market competition, and the time of market entry can all play a role in prices, in addition to other factors.

    a. Please describe how the list price is determined for your company's insulin products, including any incentives that exist in the market for high list prices.

    b. Please describe whether your company has increased or decreased the list price for each of your insulin products over the past ten years, and please also describe what factors your company considers when deciding whether to increase or decrease the list price for your insulin products.

    c. Please explain how, if at all, and increase and/or a decrease in the list price of insulin impacts patients' out-of-pocket costs for insulin products. If there is no impact on the cost of the medicine for patients, please explain.

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[21] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 2 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019.
[22] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, DIABETES CARE, at 8 (Mar. 2018), *available at* http://care.diabetesjournals.org/content/early/2018/03/20/dci18-0007.
[23] *See, e.g.*, William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 8 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019; Aimee Picchi, *The rising cost of insulin: "Horror stories every day,"* CBS NEWS (May 9, 2018), *available at* https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/.
[24] R. Scott Rappold, *Spiking Insulin Costs Put Patients in Brutal Bind* (Jul. 25, 2018), *available at* https://www.webmd.com/diabetes/news/20180725/spiking-insulin-costs-put-patients-in-brutal-bind.
[25] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 2 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019.

2. **Negotiations based on list prices for insulin**. The list price of a drug such as insulin is the starting point for negotiations that other stakeholders in the prescription drug supply chain undertake with drug manufacturers.

    a. Please describe the entities in the supply chain that your company provides some form of rebate, discount, or other price concession to for insulin products.

    b. Please describe the types, structure, and purpose of rebates, discounts, and other price concessions that your company offers to different entities in the supply chain for insulin and how your company decides whether to offer rebates, discounts, and other price concessions to different entities in the supply chain.

    c. Please describe whether there has been an increase, or decrease, in the amount of rebates, discounts, and other price concessions that your company has provided to different entities in the supply chain for insulin products over the past ten years.

    d. What is the average amount of rebate, discount, or other price concession that your company provides for each insulin product in each market (*e.g.*, commercial, Medicare Part D, etc.)?

    e. Please describe how, if at all, these rebates, discounts, and other price concessions impact patients' out-of-pocket costs for insulin products.

    f. Please describe any other negotiated fees or costs (*e.g.*, administrative fees) that are impacted by the list price of a medicine. Why are these fees based on the list price of the medicine?

3. **Value-based contracts**. Please describe whether value-based/outcomes-based contracting could be applied to insulin products.

4. **Payment and distribution systems for insulin**. The insulin supply chain is complex, and transactions throughout the insulin supply chain impact the price that individuals pay for insulin.

    a. Please describe the general distribution and payment systems for insulin and explain whether the payment and/or distribution systems for insulin differ from the typical payment and/or distribution systems used for most prescription medicines.

    b. Please describe whether the insulin supply chain could benefit from enhanced transparency.

5. **Improvements in insulin**. As you know, since insulin was discovered almost 100 years ago, there have been improvements to the medicine.[26]

    a. Please describe the investments your company has made to improve insulin and any related research and development efforts.

    b. Please describe any other investments that your company has made to help diabetic patients live longer, healthier lives.

    c. Please describe any challenges your company has faced in its attempts to improve insulin.

6. **Competition in the insulin market**. As you know, there currently are no substitutable generic forms of insulin available in the market.[27] One reason that manufacturers have struggled to bring a substitutable generic insulin to market is because insulin has traditionally been regulated as a drug rather than a biologic and it is difficult to bring a substitutable generic insulin to market under the traditional drug pathway.[28] Congress recognized this challenge when creating the new biosimilars pathway through the Biologics Price Competition and Innovation Act of 2009 (BPCIA), and Congress therefore included a provision in the law that will make it easier for manufacturers to bring substitutable generic insulins to market beginning in March 2020. Indeed, according to Dr. Gottlieb, March 2020 will be a "watershed moment for insulin products" because products that are biosimilar to, or interchangeable with, existing insulin will be able to come to market.[29]

    a. Has your company identified any additional barriers that will hinder the development of substitutable generic insulin products?

    b. Is your company aware of any current market behaviors that may harm competition in the insulin market?

    c. What additional steps, if any, could Congress and/or the FDA take to promote competition and innovation in the insulin market?

7. **Patient financial assistance programs and patient choice for insulin products.** As previously stated, many individuals with diabetes have stopped taking insulin because of increasing costs. As you know, sometimes there are programs available to help individuals purchase their medicines at a lower cost or obtain it for free.

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[26] William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care, at 2 (May 2018), *available at* http://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019.
[27] U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new actions advancing the agency's biosimilars policy framework* (Dec. 11, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628121.htm.
[28] *Id.*
[29] *Id.*

a. Does your company offer any financial assistance programs (*e.g.*, patient assistance programs, co-pay coupons) to help individuals with the cost of insulin? If so, please describe such programs, including which patient groups they are available to (*e.g.*, commercially insured, uninsured, etc.).

b. Please describe any limitations that patients have in choosing certain insulin products (*e.g.*, excluded from a formulary), and how often their choice among certain insulin products may change.

Please also make arrangements to provide a briefing to Committee staff to review your response by February 20, 2019. Please contact Natalie Turner or Caleb Graff with the Committee staff at 202-225-3641 if you have any questions about this request. Thank you for your prompt attention to this request.

Sincerely,

Greg Walden
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health

cc. The Honorable Frank Pallone
cc. The Honorable Diana DeGette
cc. The Honorable Anna Eshoo